



University of Connecticut Health Center

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Behavioral Medicine MC6228
University of Connecticut Health Center
263 Farmington Avenue
Farmington, CT 06030

December 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket #97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products.

To Whom It May Concern:

I am writing to express my concern and objection to the proposed rule that donor oocytes be used only after they become embryos, are frozen and quarantined for 6 months, and the donor has been re-tested for HIV and other sexually transmitted diseases found to be healthy.

Reasons:

1. We don't know that embryos can be a source of infection for HIV and other sexually transmitted diseases.
2. Freezing is an additional expense for patients with little justification in this instance.
3. Success rates with frozen embryos are generally 50% lower than for fresh embryos.
4. Except in states like Massachusetts that mandate insurance coverage for infertility, egg donor cycles are generally quite expensive and are out-of-pocket for patients. In these circumstances, a reduced per-cycle success rate has a huge impact.
5. Freezing kills a portion of embryos. This is an ethical issue for many patients/couples.
6. One possible financial scenario given the impact of freezing on both the viability of embryos and the pregnancy rates of cryopreserved embryo thaw cycles is that consumers may feel driven to pay to have a donor to themselves rather than to share the eggs produced in a cycle by a donor, and this almost doubles their cost.
7. When couples freeze embryos they must also make embryo disposition plans, such as donating or destroying unused embryos if they don't need all the embryos, or if they die or divorce. For some couples, none of the options are acceptable ethically or psychologically, and yet this proposed rule gives them no choices.
8. Most oocyte donation programs already have a long waiting list, generally a year or more. This rule would prolong the wait patients/couples face before they have an opportunity to conceive.

Please consider these arguments against the proposed rule.

mcjacob
Thanks very much,

97N 484S

Mary Casey Jacob, Ph.D.
Associate Professor, Psychiatry and Obstetrics and Gynecology

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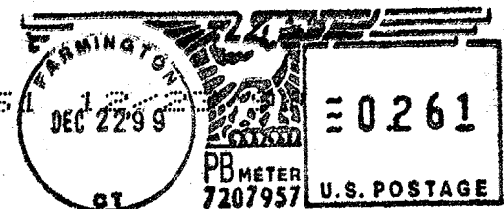
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